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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/904,190	07/10/2001	Charles William Rowe	900122.425	1220

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SEED INTELLECTUAL PROPERTY LAW GROUP PLLC
701 FIFTH AVE
SUITE 6300
SEATTLE, WA 98104-7092

EXAMINER	
PULLIAM, AMY E	
ART UNIT	**PAPER NUMBER**
1615	12

DATE MAILED: 06/12/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/904,190	ROWE ET AL.	
	Examiner	Art Unit	
	Amy E Pulliam	1615	

-- The MAILING DATE of this communication appears on the cover she t with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 March 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *11* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Receipt of Papers

Receipt is acknowledged of the Extension of Time, the Amendment B, and the Supplemental Information Disclosure Statement, received by the Office March 24, 2003, March 24, 2003, and April 22, 2003, respectively.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 7 remains rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Applicant has amended claim 7 to recite "wherein the particles of the bulk powder substance comprise at least approximately 60% by weight of the powder and 40 % by weight of the migration control substance. It is the position of the examiner that this language is still unclear. It is unclear what "powder" is being referred to in the phrase 60% by weight of the powder." Does the bulk powder contain migration controlling substance? Is there another powder being referred to? Does the bulk powder contain bulk powder material and migration controlling substance? Please clarify.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-7, 9-12, and14-18 rejected under 35 U.S.C. 102(b) as being anticipated by WO 98/36739 to Yoo *et al.*.

Yoo *et al.* disclose a rapidly dispersing dosage form, which releases its active ingredients within a period of less than about ninety seconds. Yoo *et al.* teach that the unconventional dosage forms of their invention are built through an SFF process, such as 3DP (p 4, l 27-28). Yoo *et al.* teach that the dosage form comprises a solid matrix incorporating at least one active ingredient, a bulk material and a binder, wherein the bulk material comprises at least one pharmaceutically acceptable compound in powder form, and the binder comprises a substantially water-soluble pharmaceutically acceptable substance that together with the powdered compound allows the matrix to maintain its three-dimensional structure in the absence of excess moisture (p 4, l 2-9). Yoo *et al.* teach that the process involves spreading a layer of powder, then in selected regions adding the binder to the powder particles to form layers containing solid regions, the thickness of which varies as a function of binder properties and the amount of fluid applied per unit area (p 6, l 25-30). This step is repeated until the desired number of layers for the dosage form is complete (p 7, l 1-5). Yoo *et al.* further teach that the bulk powder material can be lactose, fructose, sucrose, dextrose, sorbitol, mannitol, xylitol, and microcrystalline cellulose (p 8, l 18-20). Yoo *et al.* teach that the binder is essential to the invention, as it produces adhesion between the particles of the powder and the binder material. Yoo *et al.* teach that the binder can

be a solvent for the bulk material or a further substance that is capable of bonding to particles of the bulk compound (p 8, l 26-28). Furthermore, the binder may be included in either the powder material or in the fluid. Suitable binder material include, but are not limited to arabinogalactan, polyvinylpyrrolidone, sorbitol, mannitol, xylitol, and the like (p 9, l 3-5). Yoo *et al.* also teach that a wide variety of substances can be used as the bulk material and the binder, including water- soluble synthetic polymers (p 11, l 2-4). Yoo *et al.* also teach aqueous solutions of the binder material (p 15, l 5,6).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1- 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yoo *et al.*, as discussed above.

Yoo *et al.* are described above as teaching a rapidly dispesing dosage form, made by the process of 3DP. Yoo *et al.* further disclose that the composition used in the process comprises a bulk powder substance, a binder in solution, and a pharmaceutical agent.

Yoo *et al.* does not refer to the ingredients employed in their composition and process by the same names used by applicant. However, it is the position of the examiner that the migration controlling agents claimed by applicant are actually well known binders in the pharmaceutical art

(see below for further discussion). Therefore, the particular syntax used by applicant does not render the claims patentable.

Furthermore, Yoo *et al.* do not teach that the particle size of the migration control substance is less than 38 microns. However, it is the position of the examiner that absent a showing of criticality, the determination of a particular particle size is a manipulatable parameter as part of the process of optimization for one of ordinary skill in the art. Any unexpected results must be dependant on the particle size in order to show criticality for this particular limitation.

Additionally, Yoo *et al.* do not specifically teach that the migration control substance is methacrylate or methacrylic ester copolymer. However, it is the position of the examiner that the substances claimed by applicant as migration control substances are all well known binders in the pharmaceutical art. Furthermore, it is the position of the examiner that methacrylates are well known in the art as acceptable pharmaceutical binders. However, to reiterate this point, the examiner points to International Cosmetic Ingredient Dictionary and Handbook (Attached) which gives a list of acceptable binders. Acrylates, as well as celluloses, polyvinylpyrrolidone, xanthan gum, locust bean gum, gelatin, guar gum, and others, are all listed as appropriate binders. It is the position of the examiner that this disclosure shows equivalency between the listed compounds. Therefore, one of ordinary skill in the art would have been motivated to use any well known binder, or combination of binders in the teachings of Yoo *et al.*. The motivation lies in the teaching of equivalency. The expected result would be a successful rapidly dispersing dosage form, as taught by Yoo *et al.*.

Lastly, Yoo *et al.* does not specifically state a method of controlling binder migration. However, it is the position of the examiner again that this in only a syntax differentiation. As

stated above, it is the position of the examiner that the migration controlling substances claimed by applicant are known in the pharmaceutical art by another name, binders. Yoo *et al.* specifically state that the binder is an essential element of the invention, as it produces adhesion between particles of the powder and binder material (p 8, l 21-22). In other words, the binder prevents binder migration. Furthermore, Yoo *et al.* teach that the fluid used in the composition and process is a pharmaceutically acceptable solvent or combination of solvents, and may contain one or more binders and actives. It is the position of the examiner that Yoo *et al.* does teach a method of controlling migration, except it is not referred to by the same name. For these reasons, this invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Response to Arguments

Applicant's arguments have been fully considered but are not found to be persuasive. First, Applicant argues that Yoo do not teach a migration control substance for controlling migration of the binder fluid. Additionally, Applicant's response contains arguments drawn to a combination of references. This is confusing to the examiner as only one reference, Yoo *et al.*, is relied upon for both the anticipation and obviousness rejections.

Applicant further argues that the examiner's rejections are confusing because it is not clear how a binder which is migrating is the same binder that is itself preventing binder migration. There are several problems with this argument. First, it is the position of the examiner that claims 1-10 do not express what Applicant intends them to express. Claim 1 requires only a bulk powder substance and a migration control substance. There is nothing

present in any of claims 1-10 which requires more than one binder to be present. On the contrary, claim 1 requires a bulk powder substance, a migration control substance, and the claim refers to the presence of a binder liquid, however, this liquid need not be present to anticipate the claimed composition. Specifically, the claim refers to the presence of a binder liquid through functional language, which does not render patentable distinction to a composition claim.

Alternatively, even if claim 1 is read to require the presence of a binder liquid, the claim is still anticipated by the Yoo *et al.* reference. Claims 4 and 5 state that the binder liquid can be water or ethanol, both of which are taught by the Yoo *et al.* reference. It is not necessary that the reference use the same terminology when referring to the liquids. The examiner has interpreted "binder liquid" to mean a solvent which may dissolve the binder. Yoo *et al.* teach the use of water and ethanol for exactly that reason.

The examiner points out that none of claims 1-10 or 18-24 contain a limitation drawn to a second binder. Instead, the claims refer to a binder liquid, which can be interpreted as a solvent used for the migration controlling agent (also a binder).

It is the position of the examiner that claim 11 does not require two binders either. Claim 11 can be interpreted as a powder comprising (1) a liquid containing a binder, (2) a bulk powder substance, and (3) a migration control substance (which can be the binder found in (1)). Therefore, this claim may be interpreted to only require one binder material. This is further supported by claim 14, which states that the migration control substance and the binding substance are the same material.

It is the position of the examiner that the instant claims are still anticipated and suggested by the teachings of Yoo *et al.*. Yoo *et al.* teaches the method and the compositions claimed by Applicant. Therefore, the above rejections are maintained.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy E Pulliam whose telephone number is 703-308-4710. The examiner can normally be reached on Mon-Thurs 7:30-5:00, Alternate Fri 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on 703-308-2927. The fax phone numbers for the

organization where this application or proceeding is assigned are 703-305-3592 for regular communications and 703-305-3592 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

A. E. Pulliam
Patent Examiner
Art Unit 1615
June 9, 2003

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600